



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,372	03/12/2004	Yougandh Chitre	A04P1024	8872
36802	7590	09/06/2005	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			ROSENZWEIG, JASON	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/800,372

Applicant(s)

CHITRE ET AL.

Examiner

Jason E. Rosenzweig

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/12/2004.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 03122004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, are drawn to a method of implanting a lead system for use with an implantable cardiac stimulation device, classified in class 607, subclass 119.
 - II. Claims 8-14, are drawn to a system for implanting a lead system for an implantable cardiac stimulation device, classified in class 607, subclass 116.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the system for implanting a lead system for implantable cardiac stimulation devices could inherently be used to implant other types of leads besides those used in a cardiac stimulation device such as the gastrointestinal tract (US 6876885).

Art Unit: 3762

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. During a telephone conversation with Peter Nichols on Tuesday, August 30, 2005 a provisional election was made with no traverse to prosecute the invention of group II, claims 8-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8,9,10,11,12,13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In regards to claim 8, as per the applicants description of a "elongated stylet having an internal passage extending longitudinally through the stylet" Based upon the specification it is unclear as to if the stylus is part of the lead or lead system. In the

Art Unit: 3762

broadest interpretation it appears as if the stylus is part of the lead which would be introduced to the implantation site by the stylus while the wire guide would act as a bridge around tortuous turns. The lead therefore is part of the stylus and the two together make up a lead system which has a lumen in the stylus which allows it to slide on the outside of the guide wire. In this interpretation of the stylus and guide wire applicable prior art includes the disclosure of Brennen (US 5662119) et al. Brennen discloses: A steerable stylet assembly illustrated in FIG. 1 comprises the elongated tubular member 10 and pull wire 12 having a proximal section 14 and a distal section 16. Where in this case the pull wire resembles the guide wire in the diagram.

8. In regards to claims 9-14 they are rejected to because it is unclear to what is being claimed as there is a lack of antecedent basis for the preamble of claims 9-14 claiming "The lead system set forth in claim 8:" The preamble of the independent claim 8 refers to "A system for implanting a lead system" while the preamble of the dependent claims, 9-14 refer to "The lead system set forth in claim 8:" If applicant would like to claims related to the system for implanting a lead system it is suggested that:

Preamble of claims 9-14 should state, "A system for implanting a lead system" not "the lead system set forth in claim 8"

Art Unit: 3762

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason E. Rosenzweig whose telephone number is (571)272-5559. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason Rosenzweig
Patent Examiner
Art Unit 3762



Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3762
